

WHAT IS CLAIMED IS:

- 1 1. A system for clinical trial simulation, comprising:  
2 an interface having a fixed form module and a free form module, the  
3 interface configured to receive information that describes a trial protocol for a  
4 clinical trial simulation;  
5 a translator having a protocol parser and a code generator, the protocol  
6 parser configured to parse the trial protocol, the code generator configured to  
7 generate source code in a general purpose programming language;  
8 a compiler having a code parser and a machine code generator, the  
9 compiler configured to compile the generated source code into an executable  
10 program; and  
11 a controller communicatively coupled with the interface, the translator,  
12 and the compiler, the controller configured to run the executable program.
- 1 2. The system of claim 1, wherein the fixed form module is configured to receive  
2 trial protocol information conforming to a structured format.
- 1 3. The system of claim 2, wherein the free form module is configured to receive trial  
2 protocol information conforming to a trial design language.
- 1 4. The system of claim 1, wherein the trial protocol comprises a plurality of  
2 schedules.
- 1 5. The system of claim 4, wherein the plurality of schedules comprises a dosing  
2 schedule.
- 1 6. The system of claim 4, wherein the plurality of schedules comprises an  
2 observation schedule.
- 1 7. The system of claim 6, wherein the executable program comprises a plurality of  
2 programmable state machines.

- 1 8. The system of claim 7, wherein each state machine corresponds to a discrete one  
2 of the plurality of schedules.
- 1 9. A method for clinical trial simulation, comprising:  
2 receiving trial protocol information that describes a clinical trial  
3 simulation;  
4 arranging the trial protocol information into a plurality of schedules;  
5 translating the plurality of schedules into a general purpose, high level  
6 programming language;  
7 compiling the translated plurality of schedules into an executable program;  
8 and  
9 executing the program as part of the clinical trial simulation.
- 1 10. The method of claim 9, wherein the receiving step comprises:  
2 receiving trial protocol information that conforms to a structured format;  
3 and  
4 receiving trial protocol information that conforms to a trial design  
5 language.
- 1 11. The method of claim 9, wherein the plurality of schedules comprises a dosing  
2 schedule.
- 1 12. The method of claim 9, wherein the plurality of schedules comprises an  
2 observation schedule.
- 1 13. The method of claim 9, wherein the executable program comprises a plurality of  
2 state machines, each state machine corresponding to a discrete one of the plurality  
3 of schedules.

- 1 14. A computer readable medium having stored thereon one or more sequences of  
2 instructions for causing one or more microprocessors to perform the steps for  
3 simulating a clinical trial, the steps comprising:  
4 receiving trial protocol information that describes a clinical trial  
5 simulation;  
6 arranging the trial protocol information into a plurality of schedules;  
7 translating the plurality of schedules into a general purpose, high level  
8 programming language;  
9 compiling the translated plurality of schedules into an executable program;  
10 and  
11 executing the program as part of the clinical trial simulation.
- 1 15. The computer readable medium of claim 14, wherein the receiving step  
2 comprises:  
3 receiving trial protocol information that conforms to a structured format;  
4 and  
5 receiving trial protocol information that conforms to a trial design  
6 language.
- 1 16. The computer readable medium of claim 14, wherein the plurality of schedules  
2 comprises a dosing schedule.
- 1 17. The computer readable medium of claim 14, wherein the plurality of schedules  
2 comprises an observation schedule.
- 1 18. The computer readable medium of claim 14, wherein the executable program  
2 comprises a plurality of state machines, each state machine corresponding to a  
3 discrete one of the plurality of schedules.

- 1 19. A system comprising a microprocessor, a persistent storage area, a volatile  
2 storage area and a communication means, the system including an execution area  
3 configured to simulate a clinical trial by performing the following steps:  
4 receiving trial protocol information that describes a clinical trial  
5 simulation;  
6 arranging the trial protocol information into a plurality of schedules, the  
7 plurality of schedules comprising a dosing schedule and an observation schedule;  
8 translating each of the plurality of schedules into a general purpose, high  
9 level programming language;  
10 compiling the translated schedules into an executable program, the  
11 executable program comprising a plurality of programmable state machines, each  
12 state machine corresponding to a discrete one of the plurality of schedules; and  
13 executing the program as part of the clinical trial simulation.